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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Methyl Bromide Reproduction Study via Inhalation
EPA 55644-Q -- Caswell No. 555 -- Record 169307

TO: Walter Frances
Disinfectants Branch
Registration Division (TS-767)

FROM: William L. Burnam, Deputy Chief
Toxicology Branch
Hazard Evaluation Division (TS-769)

WLB
5/27/87

I am attaching a copy of the Dynamac review of the two-generation reproduction study carried out at American Biogenics Corp. for Great Lakes Chemical Corp.

Mr. Chitlik and myself are concerned about the protocol design that included sacrifice of adults that did not reproduce after the first breeding and request comments from the Registrant regarding this procedure. This is stated on p. 4 of the Dynamac review "Adults that did not produce litters after the first breeding were killed and necropsied". On table 4 of page 10, there is a dose-related decrease in percent of pregnant rats during the b matings and this is one of the reasons for selection of the NOEL at 3 ppm for reproductive toxicity. Note also that the number paired and mated is apparently reduced due to the above stated sacrifice procedure. Thus it appears that this procedure could have potentially confounded or reduced the sensitivity of the study to detect fertility effects. The CORE-classification and the acceptability of the study are withheld pending the receipt of the above information.

Attachment

151